



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
New England District

951576

One Montvale Avenue  
Stoneham, Massachusetts 02180  
(781) 596-7700  
FAX: (781) 596-7896

**WARNING LETTER  
NWE-04-05W**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

December 21, 2004

Carla Bartolucci, President  
Euro-USA Trading Co., Inc.  
5 Tyler Drive, P.O. Box 98  
North Franklin, CT 06254

Dear Ms. Bartolucci:

We inspected your food distribution facility, Euro-USA Trading Co., Inc., located at 5 Tyler Drive, North Franklin, Connecticut, on October 12, 2004. During the inspection, we collected samples of your product "Bionaturae Organic Fruit Spread" in various flavors: strawberry, bilberry, peach, apricot, wild berry, and plum. The inspection was conducted to determine your company's compliance with the Federal Food, Drug, and Cosmetic Act (the "Act") and its implementing regulations in Title 21 of the Code of Federal Regulations (21 CFR). You can find copies of the Act and FDA's regulations through links on FDA's Internet home page at [www.fda.gov](http://www.fda.gov).

Your varieties of Bionaturae Organic Fruit Spread products are misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] in that the labels bear the claim "No Sugar Added," but do not meet the criteria established by FDA's regulations for such a claim. The claim "No Sugar Added" is a nutrient content claim that is permitted on food labels provided that the food meets the requirements in 21 CFR 101.60(c)(2). One criteria for use of the term "No Sugar Added" is that no amount of sugar, as defined in 21 CFR 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars, is added to the food during processing or packaging [21 CFR 101.60(c)(2)(i)]. FDA's regulation in 21 CFR 101.9(c)(6)(ii) defines "sugar" as all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Your Bionaturae Organic Fruit Spread products identify "Organic Apple Juice Concentrate" as an ingredient. According to your letter entitled "Euro-USA Trading Rational for 'No Sugar Added' Claim For Its Fruit Spread-10/21/04," the "Organic Apple Juice Concentrate" ingredient in your products is used to achieve a desired level of sweetness and

“contains natural sugars found in apple juice, but it is not sugar itself.” Because apple juice concentrate is added to your Bionaturae Organic Fruit Spread products and contains sugars that functionally substitute for added sugars, your products do not meet the requirements for a “No Sugar Added” nutrient content claim and are therefore misbranded under the Act.

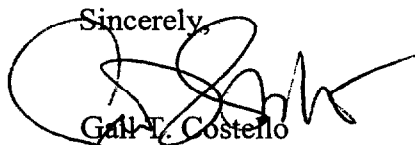
This letter is not meant to be an all-inclusive list of deficiencies for your products or their labeling. It is your responsibility to ensure that all of your products comply with the Act and implementing regulations.

You should take prompt action to correct the above-referenced violations. Failure to promptly correct these violations may result in regulatory action without further notice. The Act provides for the seizure of illegal products and/or injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the stated violations and to ensure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time at which the corrections will be completed. Your reply should be sent to Seth A. Mailhot, Compliance Officer, Food and Drug Administration, New England District Office, 1 Montvale Avenue, Fourth Floor, Stoneham, MA 02180-3500.

If you have any questions concerning this letter, please contact Mr. Mailhot at (781) 596-7769.

Sincerely,

A handwritten signature in black ink, appearing to read 'Gail T. Costello', written over the printed name.

Gail T. Costello  
District Director  
New England District Office